UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,223	09/12/2003	Stephen D. Pacetti	50623.330	9127

7590 08/26/2008

Paul J. Meyer, Jr.
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
EDWARDS, LAURA ESTELLE	
ART UNIT	PAPER NUMBER
1792	

MAIL DATE	DELIVERY MODE
08/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,223	PACETTI ET AL.	
	Examiner	Art Unit	
	Laura Edwards	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008 and 15 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 2, 4-7, and 25-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7 and 25-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-7, 25, 26, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al (US 5,836,965), hereinafter referred to as Jendersee in view Helfrich (US 5,308,338) and Scanlon et al (US 2,845,346), hereinafter referred to as Scanlon for reasons set forth in the previous office action.

With respect to claim 33, how the support surface of the member (i.e., cuff or retaining) member is made or formed to effect a porous first member to have enhanced capillary permeation goes to a method of manufacture and would not add any patentable weight to the apparatus.

With respect to claim 34, the cuff or retaining member can be formed or shaped to provide a tapered or conical shape as evidenced by Jendersee (col. 7, lines 44-45).

With respect to claim 35, while the cuff or retaining member can be formed within a balloon support surface (36), the cuff or retaining member can also be placed over the balloon support surface (36) with an inner lumen type support (34). In the event that it is not desired for the stent to contact inner lumen type support (34) directly, the stent can be provided in direct contact with outer surface of the balloon support (36). In such an instance, the third member would be defined as lumen type support (34). Also, it would have been obvious to one of ordinary skill in the art to make the third member of an appropriate size (i.e., smaller or larger) relative to the size of the stent in order to respectively, provide for minimal-contact type

processing of the stent OR to provide for maximum- contact type processing of the stent such as expansion/stretching thereof.

With respect to claim 36, the tapered design of the cuff or retaining member would provide for a cone having a narrowed portion and widened portion wherein the support (36) or support (34) would extend therebetween. The present claim language would not exclude the apparatus as set forth by the combination above to Jendersee, Helfrich, and Scanlon.

Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al (US 5,836,965) in view Helfrich (US 5,308,338) for reasons set forth in the previous office action.

The apparatus as defined by the combination above would allow for placement of the first and second members (i.e., collar or cuff or retainer) as well as the stent on the surface of the balloon catheter (36) when the first and second members are placed over the balloon support surface (36; see col. 7, lines 46-52) prior to all being fixed/adhered to the support surface (36).

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al (US 5,836,965), Helfrich (US 5,308,338), and Scanlon et al (US 2,845,346) as applied to claim 1, above and further in view of Corvi (US 5,879,499).

The teachings of Jendersee, Helfrich, and Scanlon have been mentioned above but none teach or suggest the first member (i.e., collar or cuff or retainer) being connected to a motor to rotate the first member. However, it was known in the medical or catheter art, at the time the invention was made, to provide inflation or deflation of a balloon catheter via the use of a collar

or cuff connected to a motor to translate or rotate the collar or cuff relate to the surface of the balloon catheter as evidenced by Corvi (col. 12, lines 59-63 and col. 19, lines 1-19). In light of the teachings of Corvi and the fact that the apparatus as defined by the combination establishes placement of collar or cuffs on the surface of a balloon catheter to retain a stent in place thereon, one of ordinary skill in the art would readily appreciate connection of a motor to at least one of the collars/cuffs/retaining members to provide for hands-free placement of the at least one collar/cuff/retaining member on the surface of the catheter as well as for an alternative means facilitating inflation/deflation of the balloon catheter.

Response to Arguments

Applicants' arguments filed 3/28/08 have been fully considered but they are not persuasive.

Applicants contend that a prima facie case of obviousness has not been established by the teachings of Jendersee, Helfrich, and Scanlon and if anything, the combination is unpredictable. This argument is not deemed persuasive because Applicants' instantly claimed invention only requires structure including two members with only one of the members having a pore surface, said pore surface being of the closed pore type and the other one of members having a stent support surface facing the first member (see claim 1). Jendersee establishes two facing members or cuffs or retainers (54) which can be placed along a surface of a tubular support member (36) that can support a stent. The secondary reference to Helfrich establishes in the medical art, the conventional wisdom in the variety of types of material used to make the cuffs or retainers from polymers to sintered metal and ceramics (col. 4, lines 31-39). Scanlon establishes from the

sintered metal composite art, the conventional wisdom of sintered metal bodies being made or formed in a closed pore system. In view of the teachings of Jendersee, Helfrich, and Scanlon, it would have been within the purview of one skilled in the art to provide the cuffs/retainers of Jendersee to be made of porous or even non-porous material to the extent of a closed pore construction to retain the stent ([stem] "typo") on the catheter. Thus, it would have been obvious or as Applicants recite, predictable to make the Jendersee cuffs or retainers from materials (i.e., polymers to ceramics to sintered metal) known and used to make cuffs or retainers for catheters.

Applicants contend that there is no indication in Helfrich that the porous cuffs 7, 8 (FIG. 1), 32, 33 (FIG. 6) would be appropriate for retaining a stent [stem] on Jendersee's stent [stem] delivery catheter because unlike the Jendersee catheter, the Helfrich catheter does not carry a stent [stem]. The intended use of the Helfrich catheter and/or cuffs is irrelevant because the Helfrich cuffs are known and used in the medical art, in the catheter art, and can be used in the human body.

Applicants contend that the porous cuff material in Helfrich is illustrated as being very rough (see 32, 33 in FIG. 6 reproduced below), so a person reading Helfrich would not think of using the rough cuffs to create a smooth transition in the Jendersee device (FIG. 7 reproduced above). This argument is not deemed persuasive because the texture of the cuff or the first and second members, is not claimed and therefore, the texture of the cuff being smooth, jagged, rough, etc. is not required to be taught by the prior art.

The cited references as argued by Applicants provide no teaching, no suggestion, and no motivation to make the retainer 54 of Jendersee out of a porous material and, in fact, specifically teaches away from the combination such that the examiner's suggested modification of the

Jendersee device is contrary to what any person of ordinary skill in the art would do. This argument is unconvincing because Jendersee establishes that conventional retainers be made from any implantable material (col. 7, lines 34-54) but only explicitly suggests metal or even polymers. While all of the possible implantable materials are not disclosed in Jendersee, it would be merely common sense to make the cuffs or retainers from implantable materials known and used to make cuffs or retainers in the medical art. Helfrich sets forth more materials to make the cuffs or retainers which are more implantable materials, from polymers to ceramics and even sintered metals. Helfrich does not state the porosity of the materials but Scanlon does establish as a material patent, that sintered metal can be made to be of a closed pore system (col. 1, lines 15-23. Thus, one of ordinary skill in the art would have been motivated to make the Jendersee cuffs or retainers from known materials like sintered metal even sintered metal of a closed pore construction to facilitate support of the stent on the catheter during processing whether such processing would include treatment of the stent with medicine or a therapeutic agent to placement of the stent within the body. There is no reason for not making the cuffs from various materials because all of the materials set forth are implantable or useable in the body so there is nothing to teach away from using various known and used materials to make the cuffs or retainers.

In Jendersee, Applicants contend that making the retainers 54 porous would serve no particular purpose related to retention of the stent. This argument is moot in that it does not change the logic for making cuffs from different yet known and used materials from polymers to sintered metal as established by the cited prior art to Jendersee, Helfrich, and Scanlon. One of ordinary skill in the art would readily appreciate making the cuffs from material that enables the

cuffs to retain their original function to retain the stent in place on the surface of the balloon catheter.

Applicants contend that the obviousness rejection under Jendersee, Helfrich, and Scanlon should be withdrawn because without support from the cited references, predictability or articulated reasoning for the examiner's conclusion that a porous material is suitable for Jendersee's retainers 54 is insufficient as a mater of law. See ***KSR v. Teleflex.*** This argument is not deemed persuasive in light of the responses to arguments above and in light of the fact that use of a known and suitable material (i.e., sintered metal) to make the cuffs or retainers for supporting the stent even if the material (i.e., sintered metal) results in a porous or even a non-porous material is within the purview of one skilled in the art.

Applicants contend that the obviousness rejection under Jendersee and Helfrich of claims 27-32 should be withdrawn because of the Examiner's admission (i.e., Jendersee is silent concerning the cuff(s) or retaining member(s) having a porous layer,…) but more so that tissue growth is undesirable for the Jendersee device and Jendersee does not indicate that absorption or retention of fluid is desirable for the Jendersee stent delivery catheter without sufficient rational for such an underpinning. All of Applicants arguments are well taken, in that Jendersee does not provide a listing of materials from which to make the cuffs or even the porosity of said materials. However, one of ordinary skill in the art would have determined via routine experimentation, a desired material for making the cuffs whether it be for the benefit of ease of removal of the stent when the stent is implanted into the body, whether it be for protecting the stent or whether it be for providing a smooth transition between the stent and catheter surface . The results of use of the known material, in particular, sintered metal material as suggested by Helfrich and the known

formation of sintered metal bodies as taught by Scanlon by the routineer in the art, would have provided cuffs of sintered metal having a porosity to define a closed pore system. Absent destruction or deformation of the stent, the tissue growth factor would not change the outcome of success of the cuffs to retain the stent on the balloon catheter support surface. Also, just because the prior art does not teach use of cuff materials for absorbance of coating would not make the instantly claimed invention more patentable.

Applicants inject an argument to the disinfection methodology of Helfrich catheter to there being no need for such methodology in the stent delivery catheter as in the Jendersee device. This argument is irrelevant because the Helfrich methodology is not applicable to the claimed invention and has not been applied but more so the Helfrich material has been used to establish known materials used to make cuffs/retainers in the medical/catheter art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton can be reached on (571) 272-1465. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura Edwards/
Primary Examiner
Art Unit 1792

Le
August 21, 2008